REMARKS

Claims 10, 26 and 48-52 are rejected under 35 USC 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The Examiner states that claims 1 and 3 recite a meso-lactide content of less than 1% in step (d), and claims 10, 16 and 48-52 recite a meso-lactide content of between 0 and 15%. Claims 1 and 3 are referring to a content of a purified lactide fraction, and claims 10, 16 and 48-52 are referring to a content of a prepurified lactide formed by the method. The purified lactide and the prepurified lactide are different and distinct fraction. The claims are not indefinite, and Applicant respectfully requests that the rejection be withdrawn.

Claims 1, 3, 5, 6, 9, 10, 21, 22, 25, 26, 44, 48, 49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi (US 5502215) in view of O'Brien (US 6310218).

The Examiner states that Yamaguchi does not disclose using melt crystallization to provide m-lactide content of less than 1%. The Examiner states that O'Brien teaches the process of melt crystallization can be varied to achieve maximum purity by adjust a rate of cooling during crystallization, and it would have been obvious to vary the cooling rate during crystallization of Yamaguchi to achieve a lactide product with a desired m-lactide residue. Applicant respectfully disagrees.

Claims 1 and 3 recite a process for the production and purification of lactide. Starting from an aqueous solution of lactic acid, a crude lactide product is obtained as an intermediate product from steps (a) to (c), which is further treated to yield purified lactide by melt crystallization of the crude lactide product (stage (d)) having a meso-lactide content < 1 %. Prepurified lactide is yielded by controlled crystallization in an aqueous medium (stage (e)) of the residual fractions of the melt crystallization stage (d).

Yamaguchi discloses a process for the purification of lactide. Purified lactide [1] is obtained by rapid aqueous crystallization in an aqueous medium of a crude lactide, yielding meso-lactide contents ranging from 0.5 to 2.5%, depending on the initial meso-lactide content. Optionally, re-purified lactide is obtained by subsequently dissolving and re-crystallizing the thus obtained purified lactide (= solvent crystallization), yielding meso-lactide contents of the order of $\leq$ 0.3%. Purified lactide [2] is obtained by concentrating, dissolving and re-crystallizing the residual fraction of the re-purification step (= solvent crystallization), yielding meso-lactide contents of the order of $\leq$ 0.3%. Table 1 shows the various contents of the substances.

Table 1: meso-lactide in crude, purified [1], re-purified and purified [2] lactide fractions

Crude lactide, %	***Purified Lactide [1], %***	***Re-purified lactide, %***	***Purified Lactide [2], %***
30.7 (Table 3)	2.5 (Table 4)	0.2 (Table 5)	--
31.3 (Table 6)	2.2 (Table 7)	--	--
3.0 (Table 8)	0.5 (Table 9)	~0 (Table 10)	0 (Table 11)
18.1 (Table 12)	2.1 (Table 13)	0.3 (Table 14)	
19.2 (Table 15)	2.2 (Table 16)	--	--
20.0 (Table 17)	1.5 (Table 18)	0.2 (Table 19)	0.3 (Table 20)

The Examiner states that Yamaguchi teaches melt crystallization (column 6, lines 60-65 and column 11, lines 8-10). Applicant respectfully disagrees. Melt crystallization includes cooling a molten lactide mixture to the freezing point of the lactide or slightly below, partially crystallizing the melt, forming a slurry made of a solid phase with lower impurity content and a liquid phase with a higher impurity content, and then separating the solid phase from the liquid phase. Usually, the separation of the solid phase from the liquid phase is performed simply by

gravity. In the whole process of melt crystallization, the lactide is never contacted with water or else hydrolysis of lactide would occur. On the contrary, Yamaguchi teaches to mix the slurry with cold water (column 6, lines 65-66 and column 11, lines 12-16). Yamaguchi does not teach melt crystallization, but instead teaches quench-crystallization in an aqueous medium.

In Claims 1 and 3, purified lactide with meso-lactide contents < 1% is obtained by melt crystallizing crude lactide, and pre-purified lactide is obtained by further purifying the residual fraction of the melt crystallization stage by crystallization in an aqueous medium. Yamaguchi teaches quench-crystallizing crude lactide in an aqueous medium (instead of melt crystallizing as recited in Claims 1 and 3) to yield purified lactide and discards any further purification step of the residual fractions of the first purification stage because quenching the crude lactide melt with water yields partial hydrolysis of meso-lactide, which renders it unsuitable for any further purification stages (column 7, lines 4-5). Yamaguchi teaches that it is possible to apply a second purification step to the purified lactide [1] fraction (not to the residual fraction which contains hydrolyzed lactide) to yield re-purified lactide of higher purity. Only at this stage does Yamaguchi consider that the residual fraction of the re-purification stage is worth being further purified by concentrating, dissolving, and re-crystallizing the residual fraction in a solvent to yield purified lactide [2] (= solvent crystallization). The residual fraction of the re-purification stage is already quite pure because the starting material is purified lactide [1], which shows already a high degree of purity (Tables 4, 7, 9, 13, 16, 18 in Yamaguchi). This is a completely different situation as claimed, wherein the residual fraction obtained from melt crystallizing the crude lactide is purified by crystallization in an aqueous medium.

In addition to Yamaguchi not teaching melt crystallization, the residual fraction of the water-quench crystallization purification stage taught in Yamaguchi contains hydrolyzed meso-

lactide which cannot be further purified. Therefore, regardless of whether the first purification stage taught in Yamaguchi is considered as melt crystallization or whether it is to be replaced with melt crystallization based on the teachings of O'Brien, one skilled in the art would not arrive at the claimed invention as the cited documents teach away from further purifying the residual fractions of the crude lactide purification step of Yamaguchi to yield a prepurified lactide fraction, as the meso-lactide contained in said residual fractions is partially hydrolyzed. Therefore, there is no motivation to make the proposed combination, and Claims 1 and 3 are not obvious.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi and O'Brien '218 and O'Brien (US 5521278). Claims 7, 8, 13, 14, 23, 24, 36, 37, 39-43, 46, 47, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi and O'Brien '218, O'Brien '278 and Gruber (US 6326458). Claims 7, 8, 11-14, 23, 24, 26, 37, 39-43, 46, 47, 50 and 51 depend on patentable independent claims 1 and 3 and are allowable for the reasons set forth above.

No additional fees are seen to be required. If any additional fees are due, however, the Commissioner is authorized to charge Deposit Account No. 50-1482, in the name of Carlson, Gaskey & Olds, P.C., for any additional fees or credit the account for any overpayment. Therefore, favorable reconsideration and allowance of this application is respectfully requested.

Respectfully Submitted,

CARLSON, GASKEY & OLDS, P.C.

/Karin H. Butchko/
Karin H. Butchko
Registration No. 45,864
400 West Maple Road, Suite 350
Birmingham, Michigan 48009
Telephone: (248) 988-8360
Facsimile: (248) 988-8363

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